



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

MAY -5 1999 MAY -7 1999

Mr. Fu Sheng Jin
Chinese Herb Center, Inc.
1010 Vermont Avenue, N.W.
Suite 712
Washington, D.C. 20005

Dear Mr. Jin:

This is in response to your letter of April 26, 1999, to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that the Chinese Herb Center, Inc. is making the following claims, among others, for the products:

Liverin

"It is to be used for chronic hepatitis B, C, D, E and F and carrier dietary supplement which is used for improve symptoms and SGPT...Any questions about chronic hepatitis and carrier, please call your doctors..."

Cervilin

"It is to be used for cervical syndrome such as cervical bone proliferation and degeneration. The dietary supplement is to be used for improve symptoms of cervical syndrome...Any questions about cervical bone proliferation and degeneration question, please call your TCM doctor..."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, cure, prevent, or mitigate diseases, namely, hepatitis and cervical bone disorders. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

97S-0163

LET 271

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Please contact us if we may be of further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Baltimore District Office, Office of Compliance, HFR-MA240

cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-456 (file, r/f)
HFS-450 (r/f, file)
HFD-310 (BWilliams)
HFD-314 (Aronson)
HFS-605 (Bowers)
HFV-228 (Benz)
HFV-232 (Brown)
GCF-1 (Nickerson, Dorsey)
f/t:HFS-456:rjm:5/4/99:docname:64911.adv:disc37

April 26, 1999
Mr. Fu Sheng Jin
Chinese Herb Center, Inc.
1010 Vermont NW Suite 712
Washington DC 20005
Tel: (202)393-1203

6/1/11

Dr. Elizabeth Yetley
Office of Special Nutrition
HFS-450
200 C Street, S. W.
Washington, D. C. 20204

Dear Dr. Elizabeth Yetley:

According to "Dietary Supplement Health and Education Act of 1994" Public Law 103-417, Now I write a petitioner about Liverin and Cervilin capsule (dietary supplement) to notice of structure/function class for 30 days post-market. Also I want to get permission to import to the United States of America. Although it has been delivered to the United State of America before October 15, 1994, we need to revise the "Liverin capsules" and "Cervilin capsule" labeling again.

"Liverin" capsule, "Cervilin" Capsules
Manufactured by Euro American Pharmaceutical Factory, Ltd., Hong Kong, China
Distributed by Chinese Herb Center, Inc.

I included following data for "Liverin and Cervilin" capsule for you check it, If you have any questions, Please tell me or write a letter to above address.

Sincerely Yours

Manager Mr. Fu Sheng Jin

Fu Sheng Jin

A petitioner to FDA about Cervilin

A. Identity; Composition; Physical, Chemical and Organoleptic Characteristics

1. Name of Dietary supplement

- Chemical name: not available
- Common name: Cervilin extract powder
- CAS registry number: not available

2. Chemical identity:

- Structure formula: not available
- Molecular weight: not available
- Molecular formula: not available

3. Organoleptic properties:

- Appearance: powder
- Color: brown
- Taste: not sour

4. Physical and Chemical properties:

- pH: ND
- Melting point: ND
- Water content: 1.3%
- Solubility: soluble in water.
- Specifications:

Cervilin extract is manufactured by Euro America Factory.,LTD. They sent 7 samples of Cervilin extract tablet (the batch number980802) for analysis, and they received the data from the Strasburger & Siegel, Inc., Analytical and Consulting Services 7249 National Drive Hanover, Maryland 21076. The following data

measured per capsule are listed below.

(1) Content:

(a) Average amount of impurities, toxins and pesticides in one of sample of the Cervilin extract powder

Heavy metal	Lead (Pb)	3.99 ppm
	Arsenic (As)	ND
	Cadmium (Cd)	ND
	Mercury (Hg)	<12 ppb
Others	Nitrite	ND
	Nitrate	ND

(b) Other toxins

Aflatoxin contains less than 30 ppb in the samples of Cervilin powder.

Mycotoxin: Not to be found in the 7 batch samples of above extract powder.

(c) Contaminated pesticides: ND

(d) E.Coli is less than 3

The amount of impurities and toxins and pesticides measured are lower than that specified in the FDA food standard.

B. Intended use; projected average daily intake of Cervilin capsules

1. Amount of Cervilin capsules proposed use in the United States

Projected marketing figures for Cervilin capsules have not been determined at this time.

2. Intended usage

Cervilin capsule is intended for use as a dietary supplement for cervical bone proliferation and degeneration.

3. Calculation of expected intake and daily consumption of Cervilin extract powder:

From information given by Euro American Pharmaceutical Factory., LTD, the capsule is to be taken three times a day, 6 capsules each time. Each capsule weights 500 mg, and this projects a daily consumption of 9g and yearly consumption of 3285 g for an adult.

4. Labeling

100% Natural Herb

**Cervilin
(LAM KAM SANG)**

**Hong Kong
100 Caps (500 mg each)
Natural Support For Cervical
syndrome Helper***

*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnosis, treat, cure, or prevent any disease.

Manufactured by Euro American
Pharmaceutical Factory, Ltd.

Distributed by
Chinese Herb Products, Inc.
1010 Vermont Ave, NW Suite 712,
Washington, DC 20005

Supplement Facts

Serving Size: 6 capsules

1. Rhizima Homalomenae
 2. Raix Paeoniae Alba
 3. Fructus Chaenomelis
 4. Caulis Spatholobi
 5. Flos Cathami
 6. Radix Pueratiae
 7. Pollen
 8. Fructus Ligustri Lucidi
 9. Cortex Eucommiae
 10. Phryma Leptostachya
- Above herb daily values not established

OTHER INGREDIENTS: Starch.

Recommended use:

Orally, take 6 capsules each time,
three time a day, after meal with water.

Keep out of children.

Store at a cool & dry location

Do not use If seal is broken.

Batch No:

It has been formulated by ancient Chinese medicine, and modified and refined by modern technology. It is to be used for cervical syndrome such as cervical bone proliferation and degeneration. The dietary supplement is to be used for improve symptoms of cervical syndrome. It is unique process and guaranteed potencies. Any questions about cervical bone prolifer and degeneration question, please call your TCM doctor or 202-393-1203

(2) Components:

The Cervilin extract powder contains Rhizoma Homalomenae, Raix Paeoniae Alba, Fructus Chaeonomelis, Caulis Spatholobi, Flos Carthami, Radix Puerariae, Pollen, Fructus Ligustri Lucidi, Cortex Eucommiae, Phryma Leptostachya.

Method of measurement used in above tests:

1. Official Methods of Analysis(1995), 16th Ed., AOAC International, Gaithersburg, MD
2. Bacteriological Analytical Manual (1995), 8th Ed., U.S. Food and Drug Administration, Washington, DC
3. Compendium of Methods for the Microbiological Examination of Foods(1992), 3ed., APHA, Washington, DC

All data have been certified by Strasburg & Siegel, Inc; Job NO.:811-13-198-01/08

All nutritional indexes of method numbers have been referenced from " the methods of analysis for nutrition labeling," 1993 by AOAC INTERNATIONAL.

C. The Method and result of intended Effect: Omit

D. Safety investigations (toxicological studies)

1. Overall toxicity:

As early as the 16th century, the most famous Chinese pharmacist, Shi Zhen Li, used the components of the Cervilin extract powder such as Rhizoma Homalomenae, Raix Paeoniae Alba, Fructus Chaenomeles, Caulis Spatholobi, Flos Carthami, Radix Puerariae, Pollen, Fructus Ligustri Lucidi, Cortex Eucommiae, Phryma Leptostachya to treat a lot of symptoms in human cervical bone disorder. Now this treatment has been kept till today and its efficacy is further improved by modern scientific studies. (See chart #1 and reference). Cervilin extract is manufactured with an unique process that preserves and concentrates the richest extract of fresh herb. Already there are over millions people in the world taking components of the Cervilin extract every day. Also Cervilin extract is delivered to many parts of the world, such as Europe, Africa, America, Canada and Australia, etc., and people's responses to this product have been extraordinary due to its effectiveness and safety. Each components of the Cervilin has been delivered to the United States of America before October 15, 1994. Therefore it is considered as GRAS.

According to reports based on research experiments using 5% alcohol extracts derived from two hundred selected varieties of commonly used medicinal herbs, include the components of Cervilin capsule. when said, extracts were forced to male white mice using the Linchofield and Wilcoxon method in order to determine the LD 50 of each herb, the conclusive results showed that the average LD50 was 2,000-5,000 milligrams, with the exception of raw Radix Aconniti Kusenezoffii and Semen Strychni. Thus, for most commonly used medicinal herbs and formulas, the safe dosage was found to be relatively high: for a person weighting 50 kilograms, LD 50 was approximately 250 grams; when take in normal dosage, most medicinal herbs have almost no toxicity(see reference 1). Because ten components of Cervil is very common herb. It is very safety. Based on the following acute toxic and long term test database. According to acute toxic test, they can not determine LD50 dosage in mice and Wistar big mice.

2. Acute toxicity test for Cervilin Extract Capsule

(a) The acute toxicity experiment prove that one time ingestion of 33% of the Cervilin extract for 10 mice. each mice received dosage 80g/Kg/a day for 7 days. After 7 days, they don't find any mice death and any an unusual changes in the urine, body weight, blood, liver and kidney function. Therefore they can not induce LD50 in mice. The dosages used in the toxicity studies are equivalent to 493 times of clinic dosage in human. Therefore they can not get LD50 in mice.

(b) In the second part of experiment in Wister big mice, Wister species of average weight 190+/-10 g ,half male. half female, total 20 wister big mice. one time ingestion of 80g/Kg of Cervilin extract They made with 33% Cervilin (the maximum possible concentration. The amount of ingestion is calculated from 33% of 80g/Kg body weight three times a day. For example, Wistar body weight is 190g, each Wistar mice received 15.2g Cervilin extract. After observing for 24 hours, there are no toxicity reaction and deaths occurred at this maximum dosage level. Above test shows that maximum daily dosage of 80g/kg of body weight/day in mice can be sustained for an extended period. The dosages used in the toxicity studies are equivalent to 1479 times of clinic dosage in human. Therefore they can not get LD50 in Wistar mice.

3. Long term toxicity test for Cervilin Extract Capsule:

The third part of experiment in Wister big mice, Wister species of average weight 190+/- g, half male and half female, total 20 Wister big mice. Each Wister big mice received 7.6 g Cervilin extract(equal to 40g/Kg body weight). The amount of the Cervilin used in the toxicity studies are equivalent to 245 times of clinic dosage in human. After ingestion for four months There are normal response in animal growth, blood, and index of the biochemistry ; also there are no unusual change in the organ in the pathology.

4. Impurities, byproducts(limits):

Heavy metal	Lead (Pb)	3.99 ppm
	Arsenic (As)	ND
	Cadmium (Cd)	ND
	Mercury (Hg)	<12 ppb
	Nitrite	ND
	Nitrate	ND
Other toxins	Aflatoxin B1	<30 ppb
	Mycotoxin	ND

No contaminated pesticides: ND.

5. Microbiological examination of Cervilin powder: Ecoli < 3

Reference:

1. Dr. William Chang: " Reference guide of commonly used herbal formilas". 1989.
2. Dr. Fu Sheng Jin: " The guideline for new drug application in the United States of American in Chinese" 1997.

F. Proposed tolerances

No tolerances are required to insure the safety of Cervilin capsule, because of its non-toxic nature.

G. Environmental Assessment

1. **Date:** April 26, 1999
2. **Name of Petitioner:** Chinese herb Center, Inc.
3. **Address of Petitioner:**
1010 Vermont Ave, NW Suite 712
Washington DC 20005
Tel: (202)393-1203

4. Introduction of Cervilin extract into Environment

The Cervilin powder extract capsule is manufactured in China to import into the United States. It is consumed in small quantities in households across the country, under no circumstances this capsule will cause any environmental pollution when discarded by consumer. The capsule is packaged in transparent gelatin capsule, and there are no direct or indirect additives or irradiated herbs used in Cervilin extract powder. The amount of Cervilin extract consumed or discarded in any one area will generate no toxicity and will have no impact on the local waste treatment system.

The Cervilin extract powder capsule is manufactured in Hong Kong. The manufacture states that their manufacturing process does not result in the emission of any pollutants of concern, and the process does no harm to the environment. The manufacturing process is carried out in conformance with all Chinese laws covering environmental safety, and product number for this product is to be granted by the Chinese government.

April 26, 1999
Mr. Fu Sheng Jin
Chinese Herb Center, Inc.
1010 Vermont NW Suite 712
Washington DC 20005
Tel: (202)393-1203

Dr. Elizabeth Yetley
Office of Special Nutrition
HFS-450
200 C Street, S. W.
Washington, D. C. 20204

Dear Dr. Elizabeth Yetley:

According to " Dietary Supplement Health and Education Act of 1994" Public Law 103-417, Now I write a petitioner about Liverin capsule (dietary supplement) to notice of structure/ function class for 30 days post-market. Also I want to get permission to import to the United States of America .Although it has been delivered to the United State of America before October 15,1994, we need to revise the" Livirin capsules " labeling again.

Liverin Capsules
Manufactured by Euro American Pharmaceutical Factory,Ltd., HongKong, China
Distributed by Chinese Herb Center, Inc.

I included following data for Liverin capsule for you check it, If you have any questions, Please tell me or write a letter to above address.

Sincerely Yours

Manager Mr. Fu Sheng Jin

A handwritten signature in black ink, appearing to read 'Fu Sheng Jin' in a cursive style.

A petitioner to FDA about Liverin

A. Identity; Composition; Physical, Chemical and Organoleptic Characteristics

1. Name of Dietary supplement

- a. Chemical name: not available
- b. Common name: Liverin extract powder
- c. CAS registry number: not available

2. Chemical identity:

- a. Structure formula: not available
- b. Molecular weight: not available
- c. Molecular formula: not available

3. Organoleptic properties:

- a. Appearance: powder
- b. Color: brown
- c. Taste: not sour

4. Physical and Chemical properties:

- a. pH: ND
- b. Melting point: ND
- c. Water content: 1.3%
- d. Solubility: soluble in water.
- e. Specifications:

Liverin extract is manufactured by Euro America Factory, LTD. They sent 7 samples of Liverin extract tablet (the batch number) for analysis, and they received the data from the Strasburger & Siegel, Inc., Analytical and Consulting Services 7249 National Drive Hanover, Maryland 21076. The following data measured per capsule are listed below.

(1) Content:

- (a) Average amount of impurities, toxins and pesticides in one of sample of the Liverin extract powder

Heavy metal	Lead (Pb)	3.4 ppm
	Arsenic (As)	ND
	Cadmium (Cd)	ND
	Mercury (Hg)	<12 ppb
Others	Nitrite	ND
	Nitrate	ND

- (b) Other toxins

Aflatoxin contains less than 30 ppb in the samples of Liverin powder.

Mycotoxin: Not to be found in the 7 batch samples of above extract powder.

- (c) Contaminated pesticides: ND

The amount of impurities and toxins and pesticides measured are lower than that specified in the FDA food standard.

B. Intended use; projected average daily intake of Liverin capsules

1. Amount of Liverin capsules proposed use in the United States

Projected marketing figures for Liverin capsules have not been determined at this time.

2. Intended usage

Liverin capsule is intended for use as a liver dietary supplement.

3. Calculation of expected intake and daily consumption of Liverin extract powder:

From information given by Euro America Pharmaceutical Factory., LTD, the capsule is to be taken three times a day, 3 capsules each time. Each capsule weights 430 mg, and this projects a daily consumption of 3870mg and yearly consumption of 1413.0 g for an adult.

4. Labeling

100% Natural Herb

**Liverin
(LAM KAM SANG)**

Hong Kong

100 Caps (430 mg each)

**Natural Support For Hepatitis-
Helper***

*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnosis, treat, cure, or prevent any disease.

Manufactured by Euro America
Pharmaceutical Factory,Ltd.

Distributed by

Chinese Herb Products, Inc.

1010 Vermont Ave, NW Suite 712,
Washington, DC 20005

Supplement Facts

Serving Size:3 capsules

1. Flos Mume Albud
 2. Flos Carthami
 3. Herba Abri
 4. Dendrobium Noble
 5. Pericapium Citri Reticulatae
Viride
 6. Herba Sedi Sarmentosi
 7. Herba Artemisiae Capillaris
 8. Radix Astragali Seu Hedysari
 9. Fructus Service Lucidi
 10. Rhizoma Polygoni Cuspidati
- Above herb daily values not
established

OTHER INGREDIENTS: Starch.

Recommended use:

Orally, take 3 capsules each time,
three time a day, after meal with water.

Keep out of children.

Store at a cool & dry location

Do not use If seal is broken.

Batch No:

It has been formulated by ancient Chinese
medicine, and modified and refined by
modern technology. It is to be used for
chronic hepatitis B,C,D,E and F and
carrier dietary supplement which is used
for improve symptoms and SGPT. It is
unique process and guaranteed potencies.
Any questions about chronic hepatitis and
carrier, please call your doctors or TCM
doctor or 202-393-1203

(2) Components:

The Liverin extract powder contains Flos Mume Albid, Herba Abri, Pericarpium, Fructus Ligustri Lucidi, Flos Carthami, Dendrobium Nobile, Herba Sida Serrata, Radix Astragali Seu Hedysari, Rhizoma Polygoni Cuspidatum.

Method of measurement used in above tests:

1. Official Methods of Analysis (1995), 16th Ed., AOAC International, Gaithersburg, MD
2. Bacteriological Analytical Manual (1995), 8th Ed., U.S. Food and Drug Administration, Washington, DC
3. Compendium of Methods for the Microbiological Examination of Foods (1992), 3rd., APHA, Washington, DC

All data have been certified by Strasburg & Siegel, Inc; Job NO.: 811-13-198-01/08

All nutritional indexes of method numbers have been referenced from "the methods of analysis for nutrition labeling," 1993 by AOAC INTERNATIONAL.

C. The Method and result of intended Effect: Omit

D. Safety investigations (toxicological studies)

1. Overall toxicity:

As early as the 16th century, the most famous Chinese pharmacist, Shi Zhen Li, used the components of the Liverin extract powder such as Flos Mume Albid, Herba Abri, Pericarpium, Fructus Ligustri Lucidi, Flos Carthami, Dendrobium Nobile, Herba Sedi Sarmentosi, Radix Astragali Seu Hedysari, Rhizoma Polygoni Cuspidati, to treat a lot of symptoms in human digest disorder. Now this treatment has been kept till today and its efficacy is further improved by modern scientific studies. (See chart #1 and reference). Liverin extract is manufactured with an unique process that preserves and concentrates the richest extract of fresh herb. Already there are over millions people in the world taking components of the Liverin extract every day. Also Liverin extract is delivered to many parts of the world, such as Europe, Africa, America, Canada and Australia, etc., and people's responses to this product have been extraordinary due to its effectiveness and safety. Each components of the Liverin has been delivered to the United States of America before October 15, 1994. Therefore it is considered as GRAS.

According to reports based on research experiments using 5% alcohol extracts derived from two hundred selected varieties of commonly used medicinal herbs, include the components of Liverin capsule. When said, extracts were forced to male white mice using the Linchfield and Wilcoxon method in order to determine the LD 50 of each herb, the conclusive results showed that the average LD50 was 2,000-5,000 milligrams, with the exception of raw Radix Aconiti Kusnezoffii and Semen Strychni. Thus, for most commonly used medicinal herbs and formulas, the safe dosage was found to be relatively high: for a person weighting 50 kilograms, LD 50 was approximately 250 grams; when take in normal dosage, most medicinal herbs have almost no toxicity (see reference 1). Because ten components of Liverin is very common herb. It is very safety. Based on the following acute toxic and long term test database. According to acute toxic test, they can not determine LD50 dosage in mice and Wistar big mice.

2. Acute toxicity test for Liverin Extract Capsule

(a) The acute toxicity experiment prove that one time ingestion of 33% of the Liverin extract for 10 mice. each mice received dosage 90g/Kg/a day for 7 days. After 7 days, they don't find any mice death and any an unusual changes in the urine, body weight, blood, liver and kidney function. Therefore they can not induce LD50 in mice. The dosages used in the toxicity studies are equivalent to 599 times of clinic dosage in human. Therefore they can not get LD50 in mice.

(b) In the second part of experiment in Wistar big mice, Wistar species of average weight 190 \pm 10 g, half male, half female, total 20 wistar big mice. one time ingestion of 135g/Kg of Liverin extract They made with 33% Liverin (the maximum possible concentration. The amount of ingestion is calculated from 33% of 270g/Kg body weight three times a day. For example, Wistar body weight is 190g, each Wistar mice received 50.0g Liverin extract. After observing for 24 hours, there are no toxicity reaction and deaths occurred at this maximum dosage level. Above test shows that maximum daily dosage of 270g/kg of body weight/day in mice can be sustained for an extended period. The dosages used in the toxicity studies are equivalent to 1999 times of clinic dosage in human. Therefore they can not get LD50 in Wistar mice.

3. Long term toxicity test for Liverin Extract Capsule:

The third part of experiment in Wistar big mice, Wistar species of average weight 190 \pm g, half male and half female, total 20 Wistar big mice. Each Wistar big mice received 8.6 g Liverin extract (equal to 45g/Kg body weight). The amount of the Liverin used in the toxicity studies are equivalent to 333 times of clinic dosage in human. After ingestion for four months There are normal response in animal growth, blood, and index of the biochemistry; also there are no unusual change in the organ in the pathology.

4. Impurities, byproducts(limits):

Heavy metal	Lead (Pb)	3.8 ppm
	Arsenic (As)	ND
	Cadmium (Cd)	ND
	Mercury (Hg)	<12 ppb
	Nitrite	ND
	Nitrate	ND
Other toxins	Aflatoxin B1	<30 ppb
	Mycotoxin	ND

No contaminated pesticides: ND.

5. Microbiological examination of Liverin powder: Ecoli < 3

Reference:

1. Dr. William Chang: " Reference guide of commonly used herbal formilas". 1989.

F. Proposed tolerances

No tolerances are required to insure the safety of Liverin capsule, because of its non-toxic nature.

G. Environmental Assessment

1. **Date:** April 26, 1999
2. **Name of Petitioner:** Chinese herb Center, Inc.
3. **Address of Petitioner:**
1010 Vermont Ave, NW Suite 712
Washington DC 20005
Tel: (202)393-1203

4. Introduction of Liverin extract into Environment

The Liverin powder extract capsule is manufactured in China to import into the United States. It is consumed in small quantities in households across the country, under no circumstances this capsule will cause any environmental pollution when discarded by consumer. The capsule is packaged in transparent gelatin capsule, and there are no direct or indirect additives or irradiated herbs used in Liverin extract powder. The amount of Liverin extract consumed or discarded in any one area will generate no toxicity and will have no impact on the local waste treatment system.

The Liverin extract powder capsule is manufactured in Hong Kong. The manufacture states that their manufacturing process does not result in the emission of any pollutants of concern, and the process does no harm to the environment. The manufacturing process is carried out in conformance with all Chinese laws covering environmental safety, and product number for this product is to be granted by the Chinese government..